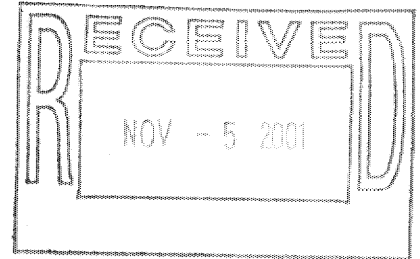




Innovative Nutrition Solutions

4420 '01 NOV 27 P1:37



October 24, 2001

Food and Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street, SW  
Washington, DC 20204

Dear Sirs:

Notice is hereby given that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Sundown brand name bearing the following statement(s) on the label and/or in the labeling:

Prostate Health: The prostate gland, located under the bladder and surrounding the urinary tract in men, is critical to optimal urinary health and sexual vitality. Saw Palmetto helps to maintain normal prostate function and urinary health. In Sundown's Prostate Health, Saw Palmetto is combined with other complementary ingredients to support prostate health...helps promote prostate health.

Vitamin E [and] Zinc: Many men eat diets that do not provide the optimum levels of crucial nutrients. Inadequate amounts of vitamins and minerals can adversely affect prostate health. Help protect yourself with these Sundown products.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

A handwritten signature in cursive script, appearing to read "Deborah Shur Trinker".

Deborah Shur Trinker, Esquire  
Senior Vice President  
Regulatory Affairs

Enclosure

97S-0162 LET 8807

6111 BROKEN SOUND PKWY. NW • BOCA RATON, FLORIDA 33487  
561-241-9400 • FAX 561-995-5188